

## **REMARKS**

### **Claim status**

Claims 1-78 were pending in the case at the time of the current Office Action. Independent claims 1, 27, and 50 are amended herein. Claims 1-78 are currently pending in the application.

### **Section 102 rejections**

In the current Office action, claims 1, 9-15, 17-21, 50, 52, 64, 69 and 77-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerber et al. (US 2004/0049240), hereinafter Gerber.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claim 1 recites a therapeutic method for treating a medical condition in a patient, said method comprising:

diagnosing a medical condition of a patient;

administering an electric nerve stimulation (ENS) therapy to a first body location of said patient; and

administering a magnetic stimulation (MS) therapy to a second body location of said patient to enhance effectiveness of said therapy,

wherein said administering of said magnetic stimulation therapy is independent of any unwanted neural activity induced by said electric nerve stimulation therapy,

and wherein said administering of said electric nerve stimulation therapy is independent of any unwanted neural activity induced by said magnetic stimulation therapy.

Independent claim 50 recites a system for providing therapeutic treatment of a neuropsychiatric disorder or other illness in a patient, said system comprising:

a magnetic stimulation (MS) subsystem to generate a pulsed current waveform to produce a pulsed magnetic field to stimulate a first region within the brain of said patient;

an electric nerve stimulation (ENS) subsystem to generate electric signals to stimulate a second region within the brain of said patient, wherein a therapeutic effect on said neuropsychiatric disorder is enhanced by a combination of said stimulating pulsed magnetic field and said stimulating electric signals; and

a computer-based switching subsystem coupled to said magnetic stimulation (MS) subsystem and said electric nerve stimulation (ENS) subsystem to select at least one of said magnetic stimulation (MS) subsystem and said electric nerve stimulation (ENS) subsystem for stimulation of the brain of the patient,

wherein said pulsed magnetic field is generated independently of any unwanted neural activity induced by said electric signals,

and wherein said electric signals are generated independently of any unwanted neural activity induced by said pulsed magnetic field.

The claimed subject matter of independent claims 1 and 50 is directed to a synergistic combination of electric nerve stimulation and magnetic nerve stimulation.

Gerber is directed to only electric nerve stimulation to relieve pain due to prostatitis and prostatodynia and does not teach or suggest magnetic nerve stimulation in the sense of the claimed subject matter of independent claims 1 and 50.

Gerber describes providing an implantable nerve stimulator (INS) comprising at least one implantable medical electrical lead for electric nerve stimulation (paragraphs [0026] and [0027]). In particular, Gerber does not teach or suggest magnetic stimulation at all in the sense of the claimed subject matter of claims 1 and 50. Instead, Gerber describes that electric leads for electric stimulation may be configured to electromagnetically or inductively couple with electromagnetic fields generated or radiated by an implantable or external pulse generator, thereby eliminating the requirement for a physical connection between the IMD (or external generator) and the electrical leads. In other words, Gerber is simply describing a wireless means of activating electrical nerve stimulation. Gerber refers to such wireless means as magnetic stimulation.

However, this magnetic stimulation (electromagnetic or inductive coupling to electrical leads) as described by Gerber is not the magnetic stimulation of the claimed subject matter of the present application. The magnetic stimulation of the present application is directed to stimulation of a body location of a patient (e.g., stimulation of a nerve or nerves) and not wireless activation of another device such as an electric nerve stimulator as in Gerber. Therefore, the claimed subject matter of the present application is directed to using both electric nerve stimulation (ENS) and magnetic stimulation (MS) of nerves and/or tissue of a patient in a synergistically combined manner to enhance effectiveness of the therapeutic treatment. Gerber does not teach or suggest any such combination of electric and magnetic stimulation and does not mention any type of enhanced or synergistic effect due to such a combination.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 and independent claim 50 are not anticipated by Gerber, and it is respectfully submitted that independent claims 1 and 50 define allowable subject matter. Also, since claims 2-26 depend either directly or indirectly from claim 1, and claims 51-78 depend either directly or indirectly from claim 50, it is respectfully submitted that claims 2-26 and 51-78 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 1, 9-15, 17-21, 50, 52, 64, 69 and 77-78 U.S.C. 102(e) be removed.

In the current Office action, claims 1, 3-4, 6-10, 12-20, 22-24, 26-29, 31-41, 43-48, 50-51, 53-55, 57-58, 61-62, 64, 69-70, and 76-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Gliner (US 2003/0074032), hereinafter Gliner.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

Independent claims 1 and 50 have been previously recited above.

Independent claim 27 recites a method of treating a neuropsychiatric disorder in a patient, said method comprising:

- applying a magnetic field to the brain of said patient; and
- administering electric nerve stimulation (ENS) therapy to the brain of the patient, wherein a therapeutic effect on said neuropsychiatric disorder is enhanced by a combination of said applied magnetic field and said administered electric nerve stimulation,
- and wherein said applying of said magnetic field is independent of any unwanted neural activity induced by said electric nerve stimulation,
- and wherein said administering of said electric nerve stimulation is independent of any unwanted neural activity induced by said magnetic field.

The claimed subject matter of independent claims 1, 27, and 50 is directed to a synergistic combination of electric nerve stimulation and magnetic nerve stimulation to enhance a therapeutic outcome.

Gliner is directed to detecting any “collateral neural activity” that may arise from a neural stimulation procedure, such as electrical stimulation or magnetic stimulation, and suppressing such unwanted induced collateral neural activity (e.g., a seizure) with response signals. However, Gliner does not teach or suggest using both electrical stimulation and magnetic stimulation together in a synergistic manner as part of the original therapeutic stimulation procedure to enhance a therapeutic outcome.

For example, in paragraph [0027], Gliner describes a first embodiment where the pulse system 160 is a component of a Transcranial Magnetic Stimulation (TMS) device that delivers

magnetic stimulation signals to a patient. Gliner then goes on to describe a second embodiment where the pulse system 160 forms a portion of an electrical stimulation device. Gliner is focused on detecting collateral neural activity in response to either electrical stimulation or magnetic stimulation, but does not describe using both electrical and magnetic stimulation together in any manner during a stimulation procedure to effect a therapeutic outcome (independent of any collateral neural activity) as does the claimed subject matter of independent claims 1, 27, and 50 of the present application.

Furthermore, Gliner does not teach or suggest a computer-based switching subsystem, or any other switching subsystem, for switching between a magnetic stimulation subsystem and an electric nerve stimulation subsystem as is claimed in claim 50 of the present application. Gliner has no need to discuss such a switching subsystem precisely because Gliner does not teach or suggest switching between or selecting at least one of magnetic stimulation and electric nerve stimulation, which are not response signals.

The claimed subject matter of the present application is not concerned with the suppression of collateral neural activity using response signals as is Gliner. Instead, with respect to the claimed subject matter of the present application, the electrical stimulation is not applied in response to any unwanted neural activity (e.g., collateral neural activity) induced by the magnetic stimulation. Similarly, the magnetic stimulation is not applied in response to any unwanted neural activity (e.g., collateral neural activity) induced by the electric stimulation.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claims 1, 27, and 50 are not anticipated by Gliner, and it is respectfully submitted that independent claims 1, 27, and 50 define allowable subject matter. Also, since claims 2-26 depend either directly or indirectly from claim 1, claims 28-49 depend either directly or indirectly from claim 27, and claims 51-78 depend either directly or indirectly from claim 50, it is respectfully submitted that claims 2-26, 28-49, and 51-78 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 1, 3-4, 6-10, 12-20, 22-24, 26-29, 31-41, 43-48, 50-51, 53-55, 57-58, 61-62, 64, 69-70, and 76-78 U.S.C. 102(e) be removed.

### Section 103 rejections

In the current Office action, claims 1-3, 5, 7, 9-10, 16, 27, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boveja (US 6,356,788), hereinafter Boveja, in view of Epstein et al. (US 6,132,361), hereinafter Epstein.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

"To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). 'All words in a claim must be considered in judging the patentability of that claim against the prior art.' *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)." MPEP § 2143.03. Additionally, as the PTO Deputy Commissioner emphasized in giving direction the Examining Corps based on *KSR International Co. v. Teleflex Inc.*, 2007 U.S. LEXIS 4745, "in **formulating a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.**" [emphasis in original].

Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness. In the outstanding Office action, the Examiner states that it would have been obvious to one having ordinary skill in the art at the time of the invention to combine a method similar to that of Boveja with a method similar to that of Epstein in order to treat multiple disorders to provide an enhanced therapy to a patient.

The claimed subject matter of the present application is not directed to treating multiple disorders at the same time as suggested by the Examiner. Instead, the claimed subject matter of the present application is directed to treating a single disorder at a time (e.g., a single medical condition such as a neuropsychiatric disorder such as depression, for example) using both electrical stimulation and magnetic stimulation "together" in a synergistically combined manner. "Together" may mean "at the same time", "one after the other", or "alternating one after the

other". Therefore, the Examiner has not provided a legitimate reason as to why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

Boveja is directed to a more adaptable and less invasive implementation of electrical stimulation as compared to the prior art. In particular, Boveja is focused on providing electrical stimulation by inductive (wireless) means at the transition into the body. Epstein is directed to improving transcranial magnetic brain stimulation (TMS) over the prior art. Epstein describes how his apparatus and method can improve the effectiveness of TMS. Boveja is totally directed to improving electrical stimulation and Epstein is totally directed to improving TMS.

Neither Boveja nor Epstein provide any teaching, suggestion, or motivation to combine electrical stimulation with magnetic stimulation in any manner, or that there would be any enhanced therapeutic effect in doing so. Electrical nerve stimulation and magnetic nerve stimulation have traditionally been distinct and competing technologies. One "skilled in the art" in electrical stimulation is unlikely to be similarly "skilled in the art" in magnetic stimulation, and vice versa, since the two technologies, even though both proposed for treating similar medical conditions, are significantly different from each other and have their own technical and application peculiarities to be considered and dealt with.

Those skilled in the art of electrical stimulation are typically focused on improving apparatus and methods for electrical stimulation. Similarly, those skilled in the art of magnetic stimulation are typically focused on improving apparatus and methods for magnetic stimulation. The two research communities (i.e., one for electrical stimulation and one for magnetic stimulation) have traditionally been significantly separate and distinct from each other, with each community trying to develop apparatus and methods for treating neurological disorders using their own distinct technologies. As such, each community tends to be biased towards its own technology and, therefore, would not likely be motivated or even interested in delving into the other's technology so as to somehow combine the two. Furthermore, it may not be unusual for a person from the electrical stimulation community to think that applying technology from the magnetic stimulation community might actually degrade the effectiveness of the electrical stimulation technology, and vice versa.

Furthermore, electrical vagus nerve stimulation for treating depression, for example, has been approved by the Food and Drug Administration (FDA), whereas TMS has not been approved by the FDA for treatment of depression. Such a disparity in regulatory approval would also likely tend to steer one skilled in the art of electrical stimulation away from getting involved in the art of magnetic stimulation, for example.

Combining electrical stimulation and magnetic stimulation in a synergistic manner in accordance with the claimed subject matter of the present application is a new paradigm developed by the Applicant and is not previously discussed or proposed in the prior art. The Applicant, being a bio-physicist who has been exposed to both technologies and yet is not firmly entrenched in one camp or the other, has come to slowly realize over time the potential benefits of combining both technologies to achieve an enhanced therapeutic effect for a given disorder. Therefore, the Applicant contends that the claimed subject matter of the present application is not obvious in light of Boveja and Epstein.

For example, the Applicant realizes that electrical stimulation of the vagus nerve produces an effect in the vagus nerve that ends at the base of the brain in the brain stem. A seizure or depression, based on many studies, originates in the cortical areas at the other end of the brain. Therefore, from the electrical stimulation of the vagus nerve, there are processes going on to allow the stimulating effect to reach the critical area in the cortex of the brain where the seizure or depression is initiated. The Applicant contends that "priming" the cortical areas of the brain with magnetic stimulation may help those critical cortical areas to receive the basic activity that originates from the brain stem area due to the vagus nerve stimulation, thus allowing the vagus nerve stimulation to be more therapeutically effective (i.e., providing a combined synergistic effect).

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claim 1 and independent claim 27 are not unpatentable over Boveja in view of Epstein, and it is respectfully submitted that independent claims 1 and 27 define allowable subject matter. Also, since claims 2-3, 5, 7, 9-10, 16 and 49 depend either directly or indirectly from claim 1 or claim



27, it is respectfully submitted that claims 2-3, 5, 7, 9-10, 16 and 49 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 1-3, 5, 7, 9-10, 16, 27, and 49 under U.S.C. 103(a) be removed.

In the current Office action, claims 25, 42, 56, 59-60, 63, 65-68 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gliner as applied to claims 6, 27 and 51 above, in view of Fox et al. (US 2003/0050527), hereinafter Fox.

Applicants respectfully traverse the foregoing rejections in view of the above pending claims and for reasons set forth hereafter.

As described above, Gliner does not teach or suggest using both electrical stimulation and magnetic stimulation together in a combined manner as part of the original therapeutic stimulation procedure to enhance a therapeutic outcome. Fox is concerned only with the delivery of transcranial magnetic stimulation.

Therefore, in view of at least the foregoing, it is respectfully submitted that independent claims 1, 27, and 50 are not unpatentable over Gliner in view of Fox, and it is respectfully submitted that independent claims 1, 27, and 50 define allowable subject matter. Also, since claims 25, 42, 56, 59-60, 63, 65-68 and 72 depend either directly or indirectly from claim 1, claim 27, or claim 50 it is respectfully submitted that claims 25, 42, 56, 59-60, 63, 65-68 and 72 define allowable subject matter as well.

Applicants respectfully request that the rejection of claims 25, 42, 56, 59-60, 63, 65-68 and 72 under U.S.C. 103(a) be removed.

#### **Allowable Subject Matter**

In the current Office action, claims 30, 71, and 73-75 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

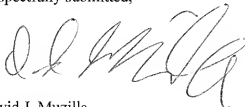
Applicants respectfully acknowledge and thank the Examiner for the above-mentioned allowable subject matter. However, Applicants believe that dependent claims 30, 71, and 73-75

are allowable because they depend either directly or indirectly from independent claims 27 or 50 which Applicants have argued herein are allowable.

Applicants respectfully request that the objection to claims 30, 71, and 73-75 be removed and that claims 30, 71, and 73-75 be recognized as allowable in their present dependent form.

Accordingly, the applicant respectfully requests reconsideration of the rejections and objections based on at least the foregoing. After such reconsideration, it is urged that allowance of all pending claims will be in order.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D. J. Muzilla', is written over a horizontal line.

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